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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,190	07/31/2001	Hiroki Moriyama	14821	3967

7590 08/15/2006

Paul J. Esatto, Jr.  
Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, NY 11530

EXAMINER
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JASTRZAB, KRISANNE MARIE

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/919,190

**Applicant(s)**

MORIYAMA, HIROKI

**Examiner**

Krisanne Jastrzab

**Art Unit**

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-949)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 5/16/2006 was filed after the mailing date of a first non-final office action after the filing of an RCE, on 3/3/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

It is noted that Applicant incorrectly indicates that the above noted IDS was filed prior to the issuance of a first office action, however, since it was certified that the information was received from a foreign patent office not more than three months prior to the filing of the IDS, the Examiner entered and considered it.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 6-63007.

JP 6-63007 teaches a tray means for high pressure sterilization of an endoscope having means for maintaining different parts of the endoscope in different positions with particular means for protecting the distal end of the insertion section from uncontrolled bending. One tray forms the lid of another when stacked cooperatively and the walls thereof have apertures and the means for protecting the distal end include cooperative concave structures. While the reference does not specifically reference the distal 70 cm portion of the endoscope, the protection of that segment of the endoscope is clearly evident. See the abstract and figures 1-4, particularly 4.

Claims 1-3, 8-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky '490 in view of Hight, III '751 and either Mönch U.S. patent No. 4,739,729 or Hauze U.S. patent No. 4,798,292.

Malchesky teaches containment of a lumened instrument with a positioning member for maintaining a predetermined bent configuration of the instrument with structure including a tray and lid, the tray having means therein to maintain the curved configuration of the instrument. Both the lid and tray, have means for the ingress and egress of sterilant, therein.

Hight, III teaches a pipe portion and a coiled portion for containment of an endoscope during sterilization in order to maintain the curved dimension of the device. Hight, III clearly teaches distal lengths inclusive of a few centimeters up to 200 cm (see

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column 3, lines 60-65), as well as maintaining the curvature of the receiving vessel to match that of the endoscope (see column 6, lines 20-25).

Both Mönch and Hauze teach the known and expected use of substantially similar containers for endoscope sterilization, in either liquid or autoclave environments, the autoclave constituting a high-pressure sterilization device. See column 3, lines 8-13 of Mönch or column 3, line 50 of Hauze.

It would have been obvious to one of ordinary skill in the art to arrange the positioning means of Malchesky such that they address the known and expected curved dimensions of lumened instruments such as endoscopes, those known dimension supported in the disclosure of Hight, III. It would further have been well within the purview of one of ordinary skill in the art to use such a container in any effective sterilizing environment, including autoclaves as supported by both Mönch and Hauze.

Claims 1-3, 8-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al., '221 in view of Hight, III '751 and either Mönch U.S. patent No. 4,739,729 or Hauze U.S. patent No. 4,798,292.

Hillebrenner et al., teach the invention substantially as claimed having a tray with a lid configured with structure to contain an endoscope in a predetermined, curved configuration. The tray and lid are hinged and latched together and having handle means. See column 2, lines 40-48 and 55-68, column 3, lines 1-35, column 6, lines 10-15, 20-25 and 45-60, column 7, lines 64-68, and column 10, lines 58-68.

It would have been obvious to one of ordinary skill in the art to arrange the positioning means of Hillebrenner et al., such that they address the known and

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expected curved dimensions of instruments such as endoscopes, those known dimension supported in the disclosure of Hight, III. It would further have been well within the purview of one of ordinary skill in the art to use such a container in any effective sterilizing environment, including autoclaves as supported by both Mönch and Hauze.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malchesky and Hight, III as applied to claims 1-3, 8-12 and 14-15 above, and further in view of Morse '758.

Morse teaches that it is known and expected to store lumened instruments in either curved or straight configurations for sterilization (see column 2, lines 20-27).

It would have been obvious to one of ordinary skill in the art to position the means within the device of the combination above such as to accommodate the instrument in a straight configuration where the curve maintenance is not essential, as this configuration is recognized as equivalent.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillebrenner et al., together with Hight, III as applied to claims 1-3, 8-12 and 14-15 above, and further in view of Morse '758.

It would have been obvious to one of ordinary skill in the art to position the means within the device of the combination above such as to accommodate the instrument in a straight configuration where the curve maintenance is not essential, as this configuration is recognized as equivalent.

***Response to Arguments***

Applicant's arguments filed 6/7/2006 have been fully considered but they are not persuasive.

Applicant argues that because Hight is directed to a liquid disinfecting system, it fails to be bound by any shape restrictions for the endoscope, however, the Examiner would disagree and would point out that Hight clearly addresses shape limitations to maintain the integrity of the endoscope during disinfection by proper and effective handling (see column 6, lines 20-25).

Applicant further argues that the apparatus of Hillebrenner is "merely rounded" and therefore does not meet the claimed limitation to "bending", however, the Examiner would disagree and maintain that "rounded" does, in fact, meet the limitation to "bending" because it is clearly curved. It is further held that the rounded configuration still suppresses the bending of another section as claimed because it holds the device to a set bend and suppresses it from any further bending beyond that.

Applicant further argues that Mose fails to meet the claimed limitation because Applicant alleges that almost the entire side of the device is bent, however, the Examiner would note that the claimed invention is to "at least the distal 70 cm", and the configuration of Mose meets that limitation, and would further note that restricting bending as claimed does not eliminate the possibility of bending, but merely "restricts" it to a particular configuration.

Finally, Applicant argues that there is no motivation to combine Hillebrenner or Malchesky with Hight because the disinfection means are not the same and alleging

that Hight teaches away from a basin type, however, the Examiner would disagree and point out that the description at column 6 of Hight, clearly does not teach away from basin type containment, and irregardless, motivationally addresses issues of effective handling and containment of endoscopes for any type of contact treatment. The teachings of Hight are properly combinable with either Hillebrenner or Malchesky.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 6/07/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent issued on application serial number 09/894,359 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/12/2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



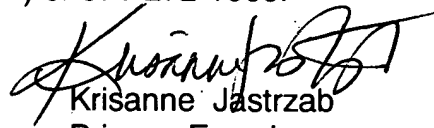
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Thurs. 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Krisanne Jastrzab  
Primary Examiner  
Art Unit 1744

August 11, 2006